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EXAMINER

OGDEN JR, NICHOLUS

ART UNIT

PAPER NUMBER

1796

MAIL DATE

DELIVERY MODE

08/12/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/722,008

Applicant(s)

TSAO ET AL.

Examiner

Necholus Ogden, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12-14 and 17-30 is/are pending in the application.
- 4a) Of the above claim(s) 25-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-14 and 17-22 is/are rejected.
- 7) ☒ Claim(s) 23 and 24 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 28, 2008 has been entered.

***Response to Amendment***

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 1, 3-4, 6, 8-10, 12, 14, 17-19 are rejected under 35 U.S.C. 103(a) as obvious over Hu et al (6,037,328) in view of Schwind et al (2002/0155961).

Hu et al disclose a method and composition for rewetting and preventing deposits on contact lens comprising an effective amount of a glucose derivative, a tyloxapol and a nonionic surfactant (col. 2, lines 45-60). Hu et al specifically disclose surfactants such as poloxamers in an amount from 0.01 to 10% by weight (col. 4, lines 50-53); and tyloxapol (col. 4, lines 65-67). Hu et al further disclose viscosity builders (col. 5, lines 37-45); preservatives or antimicrobial agents such as PHMB in an amount from 0.00001 to about 0.0015 by weight (col. 6, lines 15-20); and buffers, stabilizers or isotonic agents such as glycerol in an amount of 2.5% (col. 6, lines 33-49) to comprise an osmolality of 225 to 400 mOsm/kg a pH of 5 to 8 and buffers such as phosphates or Tris in an amount from 0.05 to 2.5% (col. 6, lines 49-59). Hu et al further include a sequestrant such as EDTA in an amount from 0.01 to 0.2% by weight (col. 6, lines 60-67). See Table I.

Hu et al is silent with respect to reducing the *C. albicans* within 15 minutes and having a log reduction of at least 1 or 1.5. However, it would have been obvious for the compositions of Hu to encompass the *C. albicans* in the requisite log reduction and time

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of contact because Hu et al teaches all of the claimed components in their requisite proportions, for the purpose of disinfecting and absent a showing to the contrary one of ordinary skill would expect similar contact lens cleaning and disinfecting characteristics.

2. Specifically, Hu is silent with respect to the sorbitol and dexpanthenol component.

Schwind et al disclose a lens care product comprising 5-20 g/l of dexpanthenol; 10 to 30 g/l of D-sorbitol; 0 to 5 g/l of sodium chloride or potassium chloride; 0.0005 to 0.05 g/l of PHMB; 0.1 to 2 g/l of EDTA; disodium phosphate buffers; water; a surface active substance; viscosifier; a pH value of 6 to 8 (see 0030-0032); 0.072 g/l of disodium hydrogen phosphate (0039) and TRIS (0014). Schwind et al further teach that the tonicity is measured in the range of 200 to 450 milliosmol (col. 1, 0007).

It would have been obvious to one of ordinary skill in the art to include the dexpanthenol and sorbitol components of Schwind et al to the compositions of Hu et al because Schwind et al teach that dexpanthenol guards against the appearance of dryness and has good cleansing action (0002) and Hu et al is concerned with preventing deposits on contact lens (see abstract). Therefore, absent a showing to the contrary, one of ordinary skill in the art would have been motivated to include the dexpanthenol for its intended purpose because only beneficial results would have been obtained.

With respect to the sorbitol component, Hu et al teach the inclusion of glycerol as tonicity agents (see above) and Schwind et al disclose sorbitol as a tonicity adjusting agent (0018) and Hu et al invite the use of tonicity agents. Therefore, one of ordinary

skill in the art would have been motivated to include the sorbitol component for its intended purposes of adjusting the osmolality and further Hu et al invite the inclusion of tonicity agents. Accordingly, in the absence of a showing to contrary, one of ordinary skill would have been motivated to include the sorbitol component of Schwind et al to the compositions of Hu et al because only beneficial results would have been obtained.

3. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hu et al (6,037,328) in view of Smith (2006/0148665).

Hu et al is relied upon as set forth above.

Specifically, Hu et al lack the specific buffer TRIS-propane.

Smith discloses an ophthalmic cleansing and antimicrobial composition and specifically teaches TRIS-propane as a buffer for said solution (015). Therefore, it would have been obvious in the absence of unexpected results to include or substitute the TRIS-propane buffer of Smith to the compositions of Hu et al because Hu et al teach and require buffers many included in the selections of Smith and one of ordinary skill would expect synergistic results in the absence of a showing to the contrary.

4. Claim 20 is rejected under 35 U.S.C. 103(a) as obvious over Hu et al (6,037,328) in view of Groemminger et al (6,872,695).

5. Hu et al is relied upon as set forth above. Specifically, Hu et al is silent with respect to the pvp component.

Groemminger et al disclose a method of cleansing contact lens comprising a thickening agent such as PVP (col. 4, line 42); surfactants such as poloxamine and

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tyloxapol (col. 4, line 66 and col. 5, line 35); an antimicrobial such as PMHB in an amount from 0.00001 to 5%; osmolality-adjusting agent such as glycerol to provide osmolality of 270 mOsm/kg and a pH of 5-6 (col. 6, lines 26-59); a sequestering or chelating agent such as EDTA (col. 6, lines 60-62) and tonicity agents such as sodium chloride in amount from 0.01 to 2.5% (col. 7, lines 1-11).

Hu et al is silent with respect to the pvp component.

Specifically, Groemminger et al teach the use of polyvinyl pyrrolidone as a thickening agent or pseudoplastic (viscosity affecting) (col. 4, line 28-42) and Hu et al require the use of substances that affect the viscosity (col. 5, lines 33-45). Therefore, one of ordinary skill in the contact lens art would have included PVP to the compositions of Hu et al to affect the viscosity of the contact lens composition as suggested by Groemminger et al for the purpose of affecting the shear liquification of gel upon blinking (col. 4, lines 27-29).

6. Claim 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable Hu et al (6,037,328) in view of Schwind et al (2002/0155961), and further in view of Groemminger et al (6,872,695).

Hu et al, Schwind et al and Groemminger et al are relied upon as set forth above. Specifically, Hu et al is silent with respect to the dexpanthenol, sorbitol and pvp components.

It would have been obvious to one of ordinary skill in the art to include the dexpanthenol and sorbitol components of Schwind et al to the compositions of Hu et al because Schwind et al teach that dexpanthenol guards against the appearance of

dryness and has good cleansing action (0002) and Hu et al is concerned with preventing deposits on contact lens (see abstract). Therefore, absent a showing to the contrary, one of ordinary skill in the art would have been motivated to include the dexpanthenol for its intended purpose because only beneficial results would have been obtained.

With respect to the sorbitol component, Hu et al teach the inclusion of glycerol as tonicity agents (see above) and Schwind et al disclose sorbitol as a tonicity adjusting agent (0018) and Hu et al invite the use of tonicity agents. Therefore, one of ordinary skill in the art would have been motivated to include the sorbitol component for its intended purposes of adjusting the osmolality and further Hu et al invite the inclusion of tonicity agents. Accordingly, in the absence of a showing to contrary, one of ordinary skill would have been motivated to include the sorbitol component of Schwind et al to the compositions of Hu et al because only beneficial results would have been obtained.

Specifically, Groemminger et al teach the use of polyvinyl pyrrolidone as a thickening agent or pseudoplastic (viscosity affecting) (col. 4, line 28-42) and Hu et al require the use of substances that affect the viscosity (col. 5, lines 33-45). Therefore, one of ordinary skill in the contact lens art would have include PVP to the compositions of Hu et al to affect the viscosity of the contact lens composition as suggested by Groemminger et al for the purpose of affecting the shear liquification of gel upon blinking (col. 4, lines 27-29), absent a showing to the contrary.

Accordingly, since each of the prior art of record teach contact lens cleansing compositions comprising many of the same well known components, the artisan of



ordinary skill would have motivated to try similar or equivalent component with the expectation that synergistic and/or beneficial results would have been obtained.

***Allowable Subject Matter***

7. Claims 23-24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

8. Applicant's arguments filed 7-28-2008 have been fully considered but they are not persuasive.

9. Applicant argues that Hu and Schwind et al do not teach the claimed components buffering agent and reducing the *C. albicans* within 15 minutes and having a log reduction of at least 1 or 1.5.

The examiner contends that Hu et al is silent with respect to reducing the *C. albicans* within 15 minutes and having a log reduction of at least 1 or 1.5. However, it would have been obvious for the compositions of Hu to encompass the *C. albicans* in the requisite log reduction and time of contact because Hu et al teaches all of the claimed components, including TRIS buffers (see above) in their requisite proportions, for the purpose of disinfecting and absent a showing to the contrary one of ordinary skill would expect similar contact lens cleaning and disinfecting characteristics.

10. Applicant argues that Groemminger does not provide further teaching that would render the invention obvious.

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11. The examiner contends that Groemminger specifically teaches that PVP is used as a viscosity improving agent and Hu invites the inclusion of viscosity agents, therefore, it would have been obvious to include the PVP ingredient for its intended purpose and absent a showing to the contrary.

An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of a case. Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not. See KSR Int'l Co. v. Teleflex Inc., 550 U.S. \_\_\_, 2007 WL 1237837, at \*12 (2007) ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.").

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Necholas Ogden, Jr. whose telephone number is 571-272-1322. The examiner can normally be reached on M-Thu.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Necholus Ogden, Jr./  
Primary Examiner  
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8-4-2008